Health Canada Santé Canada

Canadian Mammography Quality Guidelines

Canada

Canadian Mammography Quality Guidelines

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maintain and improve their health.

Health Canada

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Introduction

Breast cancer is the most frequently diagnosed cancer among Canadian women and the second leading cause of cancer death. In 1988, the National Workshop on the Early Detection of Breast Cancer made the recommendation that mammography be encouraged and offered to women aged 50 to 69 on a biennial basis. Today mammography screening programmes have been established across most Canadian provinces and territories and the number of mammograms performed yearly has increased substantially.

Mammography is currently the most accurate diagnostic modality available for the detection of breast cancer. However, in order to have an effective mammography service, it is essential that mammography be performed to meet rigorous quality requirements. A good mammography programme is one that provides the highest quality diagnostic information at the lowest radiation risk to the patient, but quality must always take precedence over radiation dose. The responsibility for the quality of mammography in Canada is shared among federal, provincial and territorial governments, and the medical professionals who carry out the procedure and interpret the films.

The purpose of this document is to provide guidance to all mammography facilities, both screening and diagnostic, to ensure mammography of the highest quality. It specifies personnel, equipment and quality assurance standards necessary to achieve and maintain a good quality film-screen mammography service. The contents of this document are built upon and harmonized with existing Canadian standards pertaining to mammography. This includes the *Diagnostic X-ray Equipment Regulations*, Part XII, of the *Radiation Emitting Devices Act*, which regulates the construction and functioning of mammographic X-ray equipment, the requirements of the Mammography Accreditation Program of the Canadian Association of Radiologists, provincial requirements, and Safety Code 33 which addresses radiation protection in mammography. It should be noted that other provincial or territorial requirements may exist that supersede or add to provisions of this document. This document does not apply to digital mammography systems.

In a field in which technology is advancing rapidly and where unexpected and unique problems continually develop, this document cannot cover all possible situations. Blind adherence to rules cannot substitute for the exercise of sound judgement. Recommendations may be modified in unusual circumstances, but only upon the advice of experts with recognized competence in radiation protection and in the operation of mammographic X-ray equipment. This document will be reviewed and revised periodically and a particular requirement may be reconsidered at any time if it becomes necessary to cover an unforeseen situation. Interpretation or elaboration on any point can be obtained by contacting the Consumer and Clinical Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1.

Personnel

The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

1. Interpreting Physicians (Radiologists)

A. (1) Initial qualifications. Unless the exemption in paragraph (2) of this section applies, before beginning to interpret mammograms independently, the interpreting physician must:

(a) possess qualifications required by any relevant Federal and Provincial regulations or statutes;

(b) be certified in Diagnostic Radiology by the Royal College of Physicians and Surgeons of Canada or by the Collège des médecins du Québec; and

(c) have sufficient training in mammography. Training shall include a minimum of 40 hours of documented American Medical Association (AMA) Category 1 credits in mammography, or Maintenance of Certification (MOCERT) evidence of learning in mammography. It is required that about half of this should be in AMA or MOCERT accredited programmes and the remainder can be in self-directed learning documented in MOCERT by submission. Time spent in residency specifically devoted to mammography is acceptable, if documentation from the training programme is supplied by the radiologist.

(2) Exemptions

(a) Radiologists, who have been in practice in Canada as of January 1998, certified by other licensing bodies and complying with provincial licensing requirements.

B. Continuing experience and education. All interpreting physicians must maintain their qualifications by meeting the following requirements:

(a) Read a minimum of 480 mammograms per year. A greater number of mammograms read per year are preferred. This requirement may be altered in low population areas where this number may not be achievable.

(b) For re-certification (after the initial 3 year accreditation), the equivalent of 15 hours of AMA Category 1 credits, or MOCERT evidence of self-directed learning in mammography in annual profiles is necessary. It is required that about half of this should be in AMA or MOCERT accreditation programmes and the remainder can be in self-directed learning documented in MOCERT by submission of a suitable annual profile. Documentation should be available upon request.

2. Mammography Technologists

A. Initial Requirements. All mammographic X-ray technologists must:

(a) possess qualifications required by any relevant Federal and Provincial regulations and statutes;

(b) be certified according to a standard, such as that of the Canadian Association of Medical Radiation Technologists (CAMRT) or the equivalent provincial license;

(c) have special training in mammography, either through the training curriculum or special courses; and

(d) be specifically trained in mammography Quality Control.

B. Continuing experience and education requirements. For re-certification (after the initial 3 year accreditation), each technologist must:

(a) have 15 hours of Continuing Education in mammography, or as required by Provincial regulations, and

(b) work the equivalent of at least 390 hours in mammography each year for 3 years, or as required by Provincial regulations. This is based on a 7.5 hour work day and a minimum of 52 days per year.

3. Medical Physicists

All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance programme shall meet the following requirements:

A. Initial Qualifications. The medical physicist must:

(a) be accredited in Medical Physics of mammography by the Canadian College of Physicists in Medicine (CCPM) or its equivalent, or any relevant provincial/territorial licence.

B. Continuing experience and education requirements.

(a) Accreditation of physicists by CCPM is for three years. To maintain accreditation, attendance of at least 15 hours of continuing education on relevant matters in mammography during these three years is required, or its equivalent.

4. Retention of Professional Records

Documentation of professional qualifications of the radiologists, mammography technologists, and medical physicists must be retained by the facility.

Equipment

All new, used and refurbished mammographic X-ray equipment, and accessories for such equipment, which are sold, imported or distributed in Canada, must conform to the requirements of the *Radiation Emitting Devices Act* and the *Food and Drugs Act* and their promulgated regulations. The applicable standards for mammography equipment under the *Radiation Emitting Devices Regulations* are published in Part XII: Diagnostic X-Ray Equipment. These standards are presented in Appendix I.

1. General

Only equipment designed specifically for mammography shall be used.

2. Equipment Information Requirements

Mammographic X-ray equipment must be accompanied by the following information, which must be provided by the manufacturer:

(a) installation instructions;

(b) the address of the manufacturer;

(c) instructions concerning any radiological safety procedures and additional precautions that are necessary because of unique features of the equipment;

(d) maintenance instructions necessary to keep the equipment in compliance with Part XII of the *Radiation Emitting Devices Regulations*;

(e) the rated line voltage, the maximum line current and the line voltage regulation for operation of the equipment at the maximum line current;

(f) the loading factors that constitute the maximum line current condition for the X-ray generator;

(g) for each X-ray tube assembly, the nominal focal spot sizes and the method of their determination, the cooling curves for the anode and for the X-ray tube housing, the X-ray tube rating charts, and the method by which the focal spot to image receptor distance can be determined;

(h) the duty cycles, rectification type and the generator rating;

(i) if the equipment is battery powered, the minimum state of charge necessary for it to operate;

(j) the operating range of X-ray tube voltages and the maximum deviation for any selected X-ray tube voltage within the range of values;

(k) if the equipment is not operated exclusively under automatic exposure control, the accuracy limits of the controlling timer, the X-ray tube current, and the current time product;

(l) where the equipment operates under automatic exposure control, the accuracy limits of that control; and

(m) the conditions under which the information provided under paragraphs (j) to (l) is valid.

3. Equipment Labelling Requirements

3. Mammographic X-ray equipment must display the following information in a manner that is legible, permanent and visible on the specified surfaces:

(a) on the external surface of the main control panel:

(i) a statement prohibiting unauthorized use and warning that hazardous X-rays are emitted when the equipment is in operation,

(ii) the X-ray warning symbol, which shall be displayed in two contrasting colours, be clearly visible and identifiable from a distance of 1 m, be at least 2 cm high and at least 2 cm wide, bear the words "CAUTION: X-RAYS — ATTENTION : RAYONS X", and conform to one of the following diagrams,

(b) with respect to the X-ray generator, the name of the manufacturer, the model designation, the serial number, the date of manufacture, and the country of manufacture;

(c) on the external surface of the X-ray tube housing, with respect to the X-ray tube assembly, the name of the manufacturer, the model designation, the serial number, the date of installation of the X-ray tube in the X-ray tube housing, the country of manufacture, and the minimum permanent inherent filtration of the X-ray beam emitted from the X-ray tube assembly, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage;

(d) on the external surface of the X-ray tube housing, or another suitable structure permanently attached to the X-ray tube housing, an indicator that enables the focal spot to image receptor distance to be determined to within 2 percent of that distance, and if the X-ray tube and the X-ray generator are not located within a common enclosure, marks that clearly indicate the anode and cathode terminals on the X-ray tube housing and on the high-voltage generator, and

(e) on the external surface of any beam limiting device that adds filtration to the X-ray beam, the total permanent filtration deliverable by the beam limiting device, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage.

B. All controls, meters, warning lights and other indicators required by Part XII of the Radiation Emitting Devices Regulations must be clearly labelled as to their function.

4. Construction Requirements

A. Mammography X-ray equipment must have

(a) a means, appropriate to its rectification type, to compensate for variation in X-ray tube voltage caused by line voltage fluctuations;

(b) a visual indicator or audible indicator that warns the operator when the variation in line voltage exceed the stated limits or a mechanism that, in that event, prevents X-rays from being emitted;

(c) on the control panel, a warning light that indicates when the equipment is ready to be energized, a second warning light that indicated when X-rays are being emitted, and if an automatic exposure control is provided, a visual indicator showing when that mode of operation is selected, or if the automatic exposure control mode is not selected or does not exist, controls and visual indicators that enable the operator to select the loading factors before an irradiation;

(d) a mechanism to initiate and terminate an irradiation;

(e) an audible signal to indicate the termination of an irradiation;

(f) a beam-limiting device;

(g) for equipment that operates within a range set out in column 1 of an item of Table 1, radiation filters that result in a measured half-value layer of aluminum, with the compression paddle in place, of not less than

(i) for each X-ray tube voltage set out in column 2 of that item, the corresponding value set out in column 3 of that item, or

(ii) in any other case, the half-value layer obtained by the following formula:

$$\text{HVL (mm of Aluminum)} \geq \frac{\text{X-ray Tube Voltage (kV)}}{100} - 0.03$$

Table 1.
Minimum half-value layer of aluminum requirement for given X-ray tube voltages

Column 1 Operating Range for Normal Use (kV)	Column 2 X-ray Tube Voltage (kV)	Column 3 Half-value Layer of Aluminum (mm)
50 or less	(a) 30	0.33
	(b) 40	0.43
	(c) 50	0.53

B. An irradiation switch which permit the emission of X-rays only when the operator exerts continuous pressure on the switch, and a controlling timer for mammography X-ray equipment which must

(a) automatically terminate an irradiation on completion of a preset irradiation time, on attainment of a preset current time product value, or on completion of a preset number of X-ray pulses;

(b) permit the operator to terminate an irradiation at any time;

(c) automatically reset itself to its original setting or to zero on termination of an irradiation; and

(d) prevent the initiation of irradiation when the timer is set at zero, at the "off" position or at an unmarked setting.

C. When a support table (including all layers, excluding the grid) is positioned between the patient and the X-ray image receptor, the aluminum equivalent of the support table shall not exceed 0.3 mm, as determined using an X-ray beam that,

(a) is generated at an X-ray tube voltage of 30 kV;

(b) has a maximum X-ray tube voltage ripple of 10 percent;

(c) has a half-value layer of aluminum of 0.3 mm; and

(d) any sensor used in automatic exposure control is considered to be part of the X-ray image receptor.

D. For mammography X-ray equipment,

(a) the X-ray tube must be securely affixed to and aligned within the X-ray tube housing;

(b) the radiation filters must be securely affixed to the exit port of the X-ray tube housing or beam limiting device, or both; and

(c) the X-ray source assembly must maintain its required position or movement without drift or vibration during operation.

E. Mammography equipment that is equipped with automatic exposure control must have

(a) a means to automatically terminate the irradiation when the current time product exceeds 1,200 mAs per irradiation; and

(b) when an irradiation under automatic exposure control terminates because the limits specified in paragraph (a) have been reached, a visual indicator or audible signal that warns the operator of the termination, and a reset control that must be activated manually before another irradiation under automatic exposure control can be made.

F. Mammography equipment must have

(a) a beam limiting device that limits the size of the X-ray beam to prevent the X-ray field, at any focal spot to image receptor distance for which the equipment operates, from extending more than 5 mm beyond the edge of the patient support next to the chest wall of the patient, and more than a distance equivalent to 2 percent of the focal spot to image receptor distance beyond any other edge of the image reception area;

(b) an image receptor supporting device that has protective shielding that limits the residual radiation, extends to the patient's chest wall, and at every other edge, extends beyond the X-ray field by at least one percent of the focal spot to image receptor distance;

(c) a breast compression device that

(i) is foot-actuated to start the compression,

(ii) permits fine adjustment of motion during the compression. (This requirement will come into effect on January 1, 2003.)

(iii) permits rapid decompression,

(iv) has motion adjustment controls on both sides of the position for the patient, and

(v) allows the portion of the compression plate in contact with the breast to be brought to within 10 mm of the surface of the patient support;

(d) an X-ray field indicator that uses light to visually define the X-ray field so that the limits of the X-ray field are visible under the ambient lighting conditions in an X-ray room;

(e) a means by which the operator may determine the focal spot to image receptor distance to within 2 percent of that distance; and

(f) two different size image receptors; and

G. Mammography equipment with a removable, fixed-aperture beam limiting device must display on its external surface the dimensions of the image reception area, and the focal spot to image receptor distance at which the beam limiting device must be used.

5. Functioning Requirements

Mammographic X-ray equipment must function in accordance with the requirements set out in sections 5A to 5I during its operation under normal conditions of use.

A. For any combination of X-ray tube voltage, X-ray tube current and irradiation time, or for any selected exposure to the X-ray image receptor, when the line voltage for each measurement is accurate to within one percent of the mean line voltage value of all measurements, and when all variable controls for the loading factors are adjusted to alternate settings and reset to the test setting before each measurement,

(a) the coefficient of variation of any 10 consecutive air kerma or exposure measurements, taken at the same point along the X-ray beam axis within a period of one hour, must be no greater than 0.05; and

(b) each of the 10 air kerma or exposure measurements taken under paragraph (a) must be within 15 percent of the mean value of those measurements.

B. This section applies in respect of mammographic X-ray equipment that has

(a) a high-voltage generator that is not a stored energy high-voltage generator;

(b) loading factors that do not change automatically to compensate for unintentional variations in X-ray tube voltage; and

(c) an irradiation time of at least 0.1 s and a current time product of at least 5 mAs.

Table 2.
Maximum deviation of loading factors for mammography equipment

Item	Column 1 Loading Factor	Column 2 Maximum Deviation from the Selected Value
1.	X-ray tube voltage	5%
2.	Irradiation time	10% plus 1 ms
3.	X-ray tube current	20%
4.	Current time product	10% plus 0.2 mAs

C. (1) The controlling timer or automatic exposure control device of mammographic X-ray equipment must have a minimum irradiation time capability that does not exceed the greater of 1/60 s, or the time required to deliver a current time product of 5 mAs.

(2) If the automatic exposure control of mammographic X-ray equipment is selected, the variation in optical density set out in subsection (3) must be determined using objects that are made of human- tissue equivalent material and have thicknesses that are representative of the actual range of the body thicknesses of the patients.

(3) For mammographic X-ray equipment, the automatic exposure control device shall perform in such a way that the variation of optical density in the resultant radiograms does not exceed the value of 0.15 of the mean optical density when the thickness of a breast tissue equivalent material is varied over a range of 2 to 6 cm and the tube voltage, and anode filter combinations are varied appropriately for such thickness. If this requirement cannot be met, a technique chart shall be developed showing appropriately loading factors for different breast thickness and compositions that must be used so that optical density within ±0.15 of the average under automatic exposure control conditions can be produced.

D. (1) For any selected value of X-ray tube voltage within a range determined in accordance with subsection (2), the quotients of the average air kerma or exposure measurement divided by the indicated current time product, obtained at the applicable settings specified in subsection (3), must not differ by more than 0.10 times their sum as determined by the formula

$$|X_1 - X_2| \leq 0{,}1\,(X_1 + X_2)$$

where X_1 and X_2 is the quotients of the average air kerma or exposure measurement divided by the current time product.

(2) The range referred to in subsection (1) is the smaller of 40 percent to 90 percent of the maximum available X-ray tube voltage, or the range of X-ray tube voltages specified for the mammographic X-ray equipment by the manufacturer.

(3) The quotients referred to in subsection (1) must be determined at

(a) if the X-ray tube current is selected in discrete steps, any two consecutive X-ray tube current settings;

(b) if the X-ray tube current selection is continuous, any two X-ray tube current settings that differ by a factor of 2 or less;

(c) if the current time product is selected in discrete steps, any two consecutive X-ray current-time product settings; or

(d) if the X-ray current time product selection is continuous, any two current time product settings that differ by a factor of 2 or less.

(4) If mammographic X-ray equipment has more than one focal spot, the quotients referred to in subsection (1) must be determined for all combinations of two focal spots that have a nominal focal spot size greater than 0.45 mm, and all combinations of two focal spots that have a nominal focal spot size equal to or less than 0.45 mm at the applicable settings set out in subsection (3).

E. (1) For mammographic X-ray equipment, the residual radiation behind the image receptor supporting device must not exceed an air kerma measurement of 1.0 μGy or an exposure measurement of 0.115 mR per irradiation when the equipment is operated at

(a) its maximum X-ray field and the minimum focal spot to image receptor distance; and

(b) its maximum X-ray tube voltage and maximum available current time product.

(2) The air kerma or exposure measurement must be averaged over a detection area that is 100 cm^2, of which no linear dimension is greater than 20 cm, centred at 5 cm from any accessible surface beyond the image receptor supporting device.

F. (1) Mammography equipment must have a minimum rate of radiation output of 7.0 mGy/s or 802 mR/s when the equipment is operated

(a) with a molybdenum anode and molybdenum filter;

(b) with the breast compression device in place between the source and the detector; and

(c) at an X-ray tube voltage of 28 kV in standard mammography mode at any focal spot to image receptor distance.

(2) The minimum rate of radiation output must be

(a) measured at a position that is 4.5 cm above the patient support; and

(b) average over a period of irradiation of 3.0 s.

G. (1) The leakage radiation from the X-ray source assembly of mammographic X-ray equipment must not exceed an air kerma rate of 1.0 mGy/h or an exposure rate of 115 mR/h when the assembly is operated at the nominal X-ray tube conditions of loading that correspond to the maximum specified energy input in one hour.

(2) The rate must be averaged over a detection area of 100 cm^2, of which no linear dimension is greater than 20 cm, that is centred at 1 m from the focal spot.

H. (1) If high voltage can appear across the X-ray tube of the diagnostic X-ray equipment, then the radiation emitting from the X-ray source assembly of the equipment must not exceed an air kerma rate of 20.0 µGy/h or an exposure rate of 2.3 mR/h when the equipment is operated with its beam limiting device fully open; and the automatic exposure control or the irradiation switch has not been activated.

(2) The rate must be averaged over a detection area of 10 cm^2, of which no linear dimension is greater than 5 cm, that is centred at 5 cm from any accessible surface of the X-ray source assembly.

I. (1) Under any operating condition, the radiation from any component of diagnostic X-ray equipment, other than the X-ray source assembly, must not exceed an air kerma rate of 20.0 µGy/h or an exposure rate of 2.3 mR/h.

(2) The rate must be averaged over a detection area of 10 cm^2, of which no linear dimension is greater than 5 cm, that is centred at 5 cm from any accessible surface of the component.

Quality Assurance

In mammography, quality assurance programme means the planned and organized actions necessary to provide confidence that mammographic equipment and related components operated in a facility will reliably produce quality mammograms providing the necessary information for accurate clinical assessment with minimum dose to patients and staff.

Quality control procedures are an essential component of quality assurance programmes which clearly specify the technical procedures necessary for the monitoring and testing of mammographic equipment and related components.

1. Quality Assurance General Recommendations

Each facility must establish and maintain a quality assurance programme.

A. **Responsible Individuals.** Although all staff members are assigned individual responsibilities, it is imperative that full cooperation exists among all concerned parties.

(a) **Owner.** The owner may be an individual, a corporation, a district, a province or some other entity. The owner has the responsibility of

(i) implementing and maintaining an effective diagnostic imaging quality assurance programme for the facility, including quality control testing procedures and record keeping;

(ii) ensuring the installation complies with all applicable regulatory requirements;

(iii) consulting with the appropriate government agencies

1. when a new facility is being constructed, or modifications of an existing one are planned, to ensure that radiation safety is adequate,

2. when mammographic X-ray equipment is purchased to ensure adequate radiation safety, and to register the equipment with the appropriate agency, and

3. to set periodic scheduled inspections for the facility. In some jurisdictions, the agency responsible for inspections has the mandate for setting inspection schedules;

(iv) establishing safe working conditions;

(v) ensuring that

1. the equipment functions properly through ongoing maintenance by competent personnel and replacement of outdated or noncompliant equipment,

2. safe operating procedures are established and are followed,

3. quality control monitoring of mammographic X-ray equipment, image processor, and ancillary equipment is carried out,

4. technologists are properly trained in the operation of the equipment being used, and

5. technologists-in-training and inexperienced personnel operate mammographic X-ray equipment only under the direct supervision of a licensed or certified technologist; and

(vi) ensuring professional qualifications are maintained.

(b) **Interpreting Physicians (Radiologists).** All interpreting physicians must

(i) participate fully in the quality assurance programme

(ii) communicate with staff any changes in image quality whether they are due to improper positioning, loading factors or image processing.

(c) **Medical Physicists.** The medical physicist is responsible for

(i) verifying the safety of an installation at the time of planning and construction, and ensuring that the installation complies with all applicable regulatory requirements;

(ii) providing ongoing evaluations of the safety procedures and recommending to the owner the necessary changes to ensure optimum patient and personnel safety, and instructing personnel in proper radiation protection practices;

(iii) participating in the quality assurance programme to

1. ensure that the quality assurance programme is properly implemented and operated;
2. verify whether the optimal level of technical image quality is obtained; and
3. ensure appropriate quality control monitoring instruments are available and properly calibrated;

(iv) performing the required testing of mammographic X-ray equipment, image processor, and ancillary equipment according to the proper record keeping procedures described in section (B);

(v) providing a complete written report clearly describing survey results; and

(vi) prompt oral communication of survey results with a responsible individual within the facility.

(d) **Mammography Technologist.** Mammography technologists must participate fully in the quality assurance programme by

(i) ensuring that the optimal level of diagnostic image quality is maintained,

(ii) performing daily and routine quality control tests of mammographic X-ray equipment, image processor, and ancillary equipment and keeping records of these tests, and

(iii) communicating with staff any changes in image quality.

B. **Quality Assurance Records.** It is essential that measurements and information gathered for the quality assurance programme be clearly documented and readily available for evaluation.

(a) The medical physics report should be circulated to all staff and retained at the facility.

(b) As fas as practicable, recorded data must be indicated as data points on a control chart when the measurement is made. In this form, trends can be more easily detected. A log book or other easily identifiable method of recording must be used and records must be keep for a minimum of 3 years.

(c) Processor quality control charts should be retained in the Quality Control records for 1 year.

(d) Sensitometric films for the last full months Quality Control chart should be retained.

(e) One monthly sample Quality Control phantom film must be keep for a minimum of 3 years.

C. **Evaluation of Data.** Recorded data must be evaluated immediately and necessary action taken expeditiously.

D. **Baseline Performance Levels.** Baseline performance values of mammographic X-ray equipment and image processing system must be established after verifying that equipment functions properly. Images used for determining baseline performance levels should be obtained using the routine technique for a 4.2 cm compressed breast. This baseline performance will be used to diagnose any changes in equipment performance. It is important to keep records of equipment operation data and baseline performance measurements. These records will be needed to diagnose any changes in image quality.

E. **Testing Frequency.** The frequency of testing should be increased if the equipment exhibits significant changes between scheduled Quality Control tests, or if the equipment is used for an exceptionally high volume of procedures. Additional testing should be performed if the results of testing fall outside the limits of acceptability for the tests, or after any corrective actions are made. Equipment must be retested after service to any part which may affect the image density, image quality or radiation output from the X-ray tube.

The Quality Control programme should not be discontinued if the results indicate relatively stable equipment performance. The purpose of a Quality Control programme is to control quality, and periodic measurement of equipment performance is essential. The frequency of testing described in sections (3) and (4) should be considered a minimum.

F. **Corrective Actions.** There must be established repair and calibration procedures to deal with significant problems. A decision tree system should be developed to provide guidance to deal with events such as equipment failure and to deal with circumstances when equipment performance deviates beyond the set limits. A list of individuals having the authority to stop operation of a mammographic unit should be established. The decision tree should include the following steps:

(i) repeat test to confirm;

(ii) what to do if repeated test confirms performance failure;

(iii) what to do if test fails only marginally;

(iv) what to do if test shows a history of failure; and

(v) what to do if test fails substantially.

2. Quality Assurance – Equipment Requirements

It is essential that the necessary quality control test equipment be provided to the quality control technologist or medical physicist. It is suggested that the required test equipment be acquired when mammographic X-ray equipment is purchased. A complete list of test equipment is shown in Table 3 along with purchasing specifications for the accuracy and reproducibility of the equipment.

If the facility elects to perform all quality control tests, including testing carried out during implementation of the programme to establish baseline values, daily quality control monitoring, and tests to verify the ongoing performance of the mammographic X-ray system, items 1-20 of the test equipment listed in Table 3 are required.

If the facility elects instead to only perform daily quality control testing and some of the tests to verify the ongoing performance of the mammographic X-ray system, only items 1-12 of the test equipment listed in Table 3 are required. Although it is recommended that all equipment be available at each facility, only daily quality control equipment, items 1-6, must be present on-site and items 7-12 should be accessible when needed. It is assumed that the organization or individual which provides testing services will be responsible for supplying their own test equipment, items 13-20.

Table 3.
Quality Control Equipment

Item		Equipment	Accuracy	Reproducibility
1	Test Equipment for Daily Quality Control Tests	Sensitometer (21 step optical attenuator with densities ranging from approximately 0.00 to 4.80 in steps of 0.15)	± 0.02 log exposure units	± 0.02 log exposure units
2		Densitometer	± 0.02 O.D. at 1.0 O.D.	± 0.01 O.D. at 1.0 O.D.
3		Thermometer	± 0.3 °C	± 0.1 °C
4		Magnifying glass	—	—
5		Ultraviolet light	—	—
6		Uniform 3-5 cm thick cassette-sized phantom (acrylic)	—	—
7	Test Equipment for Monthly and Quarterly Quality Control Tests	Phantom, with image quality evaluation objects (RMI-156 or NA #18-220 are required for accreditation by MAP)	—	—
8		Compression force test device	± 10%	± 5%
9		Stopwatch	—	—
10		Film/screen contact test tool (16 mesh/cm or 40 mech/in)	—	—
11		Fixer retention test kit	—	—
12		Ruler	—	—
13	Test Equipment for Annual Quality Control Tests	Dosimeter	± 5%	± 1%
14		Non-invasive X-ray tube voltage meter	± 1.5 kV	± 0.5 kV
15		Irradiation time meter	± 5%	± 1%
16		Light meter (for measurement of luminance and illuminance)	± 10%	± 5%
17		Aluminum filter (> 99.9% purity)	1% thickness	—
18		Resolution test pattern for focal spot assessment (maximum resolution of at least 16 lp/mm)	—	—
19		Sheets of uniform breast equivalent material (at least four 2 cm thick sheets)	—	—
20		Metallic coins	—	—

3. Quality Assurance – Mammography Technologists' Quality Control Tests

A. **Daily Quality Control Tests.** Daily Quality Control tests must be performed at the beginning of each day that mammography is conducted before processing any patient films.

(a) In order to maintain the cleanliness of the darkroom all working surfaces, tops of counters and the floor should be cleaned daily.

(b) Film processor function must be evaluated every morning before performing clinical examinations, after the processor has been turned on and has reached the required development temperature; and at other times as required, such as after a replenishment rate change.

(i) The film processing solution levels must be checked to ensure agreement with the manufacturers' recommended baseline levels for the particular processor and film type, for the given number of films processed daily.

(ii) The film processing solution temperature must be checked, using a non-mercury thermometer, to ensure agreement with the manufacturers' recommended baseline level for the particular processor and film used.

(iii) Sensitometric strip processing must be performed in order to monitor the performance of the image processing system.

1. The base plus fog shall be within +0.03 of the established operating level.
2. The mid-density shall be within ±0.15 of the established operating level.
3. The density difference shall be within ±0.15 of the established operating level.

(c) Image quality evaluation tests should be performed. A uniform phantom representing average breast thickness should be routinely used to monitor and maintain image density to ensure correct optical density, the absence of excessive artifacts, and a consistent current time product setting. *While it is strongly recommended that this test be performed daily, this test must be performed at least weekly.*

(i) The optical density of the film at the centre of an image of a phantom shall be at least 1.40 when exposed under a typical clinical condition. It is strongly recommended that the optical density be greater than 1.60.

(ii) The optical density of the film at the centre of the phantom image shall not change by more than ±0.20 from the established operating levels.

B. **Weekly Quality Control Tests**

(a) A visual test must be performed in the darkroom to ensure the room is light tight. Particular attention must be paid to the door seal and the mounting of the film processor if the film insertion to the processor is done through a wall.

(b) Screens should be checked for cleanliness and damage. Manufacturer recommended screen cleaner should be used. An inspection for dust particles should be done with an ultraviolet light.

(c) Cassettes should be checked for cleanliness, wear, warping, fatigue of foam compression material and closure mechanism, light leaks.

(d) The cassette holder tunnel should be checked for dust and dirt.

(e) Viewboxes should be inspected visually for cleanliness, viewing area discolouration and improper illumination.

(f) A phantom, with image quality evaluation objects, should be used to test imaging performance of the mammographic X-ray system. *While it is strongly recommended that this test be performed weekly, this test must be performed at least monthly for the accreditation phantom.*

(i) A minimum of the four largest fibres, the three largest speck groups and the three largest masses must be visible.

(ii) The number of test objects of each group type (fibres, specks, and masses) visible in the phantom image should not decrease by more than one half.

(iii) The phantom image background optical density should be at least 1.4 and should not vary by more than ±0.20 from the operating level.

(iv) The density difference due to a 4.0 mm acrylic disc should be at least 0.40 and should not vary by more than ±0.05 from the established operating level.

C. **Monthly Quality Control Tests**

(a) X-ray equipment should be visually inspected for loose or broken components.

(b) The accuracy of the processor temperature display should be checked regularly against a non-mercury thermometer. The processor developer temperature should be accurate to within 0.5 °C.

(c) The replenishment rate must be compared with the manufacturers' recommended baseline level for the particular processor and film type, for the given number of films processed daily and for the method of processing.

D. **Quarterly Quality Control Tests**

(a) Fixer retention tests should be performed to ensure fixer is adequately removed from processed films according to established baseline levels.

(b) An analysis must be done of the repeat records to identify and correct any trends or errors. The repeat rate must be between 2 and 5 percent, not including Quality Control films. Facilities must maintain records for every repeat by recording every repeat, including the reason for the repeat along with any corrective actions, immediately after the repeat film is taken. If images contain some patient diagnostic information, they should be maintained in the patient file.

E. **Semi-Annual Quality Control Tests**

(a) Breast Compression Device. A compression force of at least 11.4 kg (25 lbs) shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive must be between 11.4 kg (25 lbs) and 20.5 kg (45 lbs).

(b) Level of Film Base Plus Fog. The level of optical density from the base material and film must not be greater than 0.25 units.

(c) Safelight Test for Darkroom Fog. An image of a uniform cassette-sized phantom exposed to a minimum optical density of 1.4 units must not show an increase in optical density greater than 0.05 units in two minutes exposure to the darkroom light environment.

(d) Screen/Film Contact. All cassettes used in mammography must be tested for screen/film contact using a 16 mesh/cm (40 mesh/in) copper screen. Large areas greater than 1 cm in diameter of poor contact that are not eliminated by screen cleaning and remain in the same location during subsequent tests should replaced. Multiple small areas, less than 1 cm in diameter, are acceptable.

4. Quality Assurance – Medical Physicists' Mammographic Quality Control Tests

A. **Annual Quality Control Tests**

(a) X-ray Tube Radiation Output. The X-ray tube radiation output shall be high enough to minimize irradiation time to eliminate perceptible motion artifacts.

(i) For any combination of operating loading parameters, the coefficient of variation of any ten consecutive radiation exposure measurements, taken at the same source to detector distance within a time period of one hour, must be no greater than 0.05, and each of the ten radiation exposure measurements must be within 15 percent of the mean value of the ten measurements.

(ii) For film-screen mammography equipment, the X-ray tube output should be at least 7.0 mGy/s (802 mR/s) over a 3 second period of time when operating at 28 kV in the standard mammography (Mo/Mo) mode at any clinically used Source to Image Distance (SID).

(b) Radiation Beam Quality. The first half-value layer should be determined for all commonly used clinical X-ray tube voltages and target/filter combinations. The unit should be set to manual timing, with a time sufficiently long to provide an air kerma of approximately 4.5 mGy when there is no aluminum filtration placed in the beam.

(i) The first half-value layer of aluminum, measured with the compression paddle in place, shall not be less than the values shown in Table 4 for a selected X-ray tube voltages and all target/filter combinations. For other X-ray tube voltages, the half-value layer of the radiation beam must be calculated by linear interpolation from the values in Table 4, by using the following formula:

$$HVL \ (mm\ of\ Aluminum) \geq \frac{X\text{-}ray\ Tube\ Voltage\ (kV)}{100} + 0.03$$

(ii) The first half-value layer of aluminum, measurement without the compression paddle in place, shall not be less than the values shown in Table 4 for selected X-ray tube voltages and all target/filter combinations. For other X-ray tube voltages, the half-value layer of the radiation beam must be calculated by linear interpolation from the values in Table 4, or by using the following formula:

$$HVL \ (mm\ of\ Aluminum) \geq \frac{X\text{-}ray\ Tube\ Voltage\ (kV)}{100}$$

Table 4.
Minimum first half-value layer for selected X-ray tube voltage at any combinations of target and filter materials when measured with and without the compression paddle in place.

X-ray Tube Voltage (kV)	Minimum First Half-Value Layer with Compression Paddle in Place (mm Al)	Minimum First Half-Value Layer without Compression Paddle in Place (mm Al)
24	0.27	0.24
26	0.29	0.26
28	0.31	0.28
30	0.33	0.30
35	0.38	0.35

(iii) The first half-value layer of aluminum, measured **with the compression paddle** in place, should not be greater than the values obtained using the following formula for a selected X-ray tube voltage:

$$HVL\ (mm\ of\ Aluminum) < \frac{X\text{-}ray\ Tube\ Voltage\ (kV)}{100} + C$$

where
C = 0.12 mm Al for Mo/Mo,
C = 0.19 mm Al for Mo/Rh,
C = 0.22 mm Al for Rh/Rh, and
C = 0.30 mm Al for W/Rh.

Note that these half-value layer upper limits are based on molybdenum filter thicknesses of 30 µm or less and rhodium filter thicknesses of 25 µm or less.

(c) Automatic Exposure Control System – Optical Density Setting Response. The automatic exposure control device must perform in such a way that the variation of optical density in the resultant radiograms does not exceed ± 0.15 of the mean optical density when the thickness of a uniformly attenuating breast tissue equivalent material is varied over a range of 2 to 6 cm and the tube voltage, and anode filter combinations are varied appropriately over the range used clinically in the facility. The optical density of the film in the centre of the phantom image shall not be less than 1.20. If this requirement cannot be met, a technique chart shall be developed showing appropriately loading factors for different breast thickness and compositions that must be used so that optical density within ±0.15 of the average under automatic exposure control conditions can be produced.

(d) Screen/Film Speed Uniformity. The film optical density must be within ± 0.15 units from the mean for all cassettes used in the facility when tested with identical loading factors.

(e) Representative Breast Surface Dose and Mean Glandular Dose Calculations. Breast phantoms such as RMI-156 or NA #18-220 which represent a breast composed of 50 percent fat and 50 percent glandular tissue and compressed to 42 mm thickness, should be used to determine the representative mean glandular dose for a breast of similar composition. The mean glandular dose should not exceed 3.0 mGy.

(f) Focal Spot Conditions – System Resolution. The X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of

(i) 11 line-pairs/mm when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and

(ii) 13 line-pairs/mm when the bars are parallel to the axis.

The bar pattern shall be placed 4.5 cm above the breast support surface, centred with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest-wall edge of the image receptor.

When more than one target material is provided, the measurement shall be made using all possible combinations of focal spot and target material. When more than one SID is provided, the test shall be performed at the SID most commonly used clinically. The test X-ray tube voltage shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available.

If necessary, a suitable absorber may be placed in the beam to increase the exposure time. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(g) Beam Limiting Device. For any focal spot to image receptor distance, the x-ray field does not extend beyond

(i) the edge of the patient support next to the chest wall of the patient by more than 5 mm, and

(ii) any other edge of the image reception area by more than 2 percent of the focal spot to image receptor distance.

(h) Light Field Alignment. If a light localizer designed to define the outline of the X-ray field is included, the separation between the perimeter of the visually defined field and that of the X-ray field must not exceed 2 percent of the focal spot to image receptor distance.

(i) Viewboxes. All viewboxes used for the interpretation of mammograms must be tested for compliance with the following requirements. Ensure all viewboxes have been turned on for a minimum of 30 minutes before obtaining measurements.

(i) Brightness. The view box brightness should be at least 3,500 nits (cd/m^2).

(ii) Light Output Uniformity. The light output from the viewboxes should be uniform to within 10 percent.

(iii) Light Output Homogeneity. The light output homogeneity between all viewboxes used for mammograms should be uniform to within 15 percent of the mean.

(iv) Ambient Light Control. The ambient light within the reading room must be less than 50 lux. A value of 5-10 lux is recommended.

Appendix I:
Radiation Emitting Devices Regulations;
Part XII, excerpt for mammography X-ray Equipment

Diagnostic X-ray Equipment

Interpretation

1. (1) The definitions in this subsection apply in this Part.

"aluminum" means aluminum that has a degree of purity of 99.9% or higher and a density of 2.70 g/cm^3. (*aluminium*)

"aluminum equivalent" means the attenuation equivalent of an object expressed in thickness of aluminum. (*équivalent en aluminium*)

"field emission device" means a device in which the emission of electrons from the cathode is due solely to the action of an electric field. (*dispositif d'émission par effet de champ*)

"loading factor" means a factor the value of which influences the X-ray tube load, and includes

(a) for diagnostic X-ray equipment, if the X-ray beam is produced by the discharge of the capacitor through an X-ray tube, the X-ray tube voltage and the amount of capacitor charge;

(b) for a field emission device, the X-ray tube voltage and the number of pulses; and

(c) for any other diagnostic X-ray equipment, the X-ray tube voltage and

(i) the X-ray tube current and irradiation time, or

(ii) the current time product. (*paramètre de charge*)

"mammography equipment" means diagnostic X-ray equipment that is used for the examination of breast tissue. (*appareil à mammographie*)

"mobile equipment" means, with respect to diagnostic X-ray equipment, equipment that is moved between incidents of use. (*appareil mobile*)

"radiographic equipment" means diagnostic X-ray equipment that implements a technique in which the information contained in the X-ray pattern is obtained, recorded and optionally processed. (*appareil de radiographie*)

"rectification type" means, with respect to diagnostic X-ray equipment, the process by which the X-ray generator converts high voltage to X-ray tube voltage. (*type de redressement*)

"X-ray image receptor" means a device that converts incident X-rays into a visible image or into a form that can be made into a visible image by further transformation. (*récepteur d'image radiologique*)

(2) Unless otherwise defined, words and expressions used in this Part have the same meaning as in the International Electrotechnical Commission Standard entitled *Medical radiology – Terminology*, Publication 788, First edition, 1984.

Information and Labelling

Information

2. The manufacturer must ensure that the following information accompanies each piece of diagnostic X-ray equipment:

(a) the installation instructions;

(b) the address of the manufacturer;

(c) any radiological safety procedures and additional precautions that are necessary because of any unique features of the equipment;

(d) the maintenance instructions necessary to keep the equipment in compliance with the requirements of this Part;

(e) the rated line voltage, the maximum line current and the line voltage regulation for the operation of the equipment at the maximum line current;

(f) the loading factors that constitute the maximum line current condition for the X-ray generator;

(g) for each X-ray tube assembly,

(i) the nominal focal spot sizes and the method of their determination,

(ii) the cooling curves for the anode and for the X-ray tube housing,

(iii) the X-ray tube rating charts, and

(iv) the method by which the focal spot to image receptor distance can be determined using the indicator specified in subparagraph 3(c)(i);

(h) its duty cycles, rectification type and generator rating;

(i) if the equipment is battery powered, the minimum state of charge necessary for it to operate;

(j) the operating range of X-ray tube voltages and the maximum deviation for any selected X-ray tube voltage within that range of values;

(k) if the equipment is not operated exclusively in automatic exposure control mode, the accuracy limits of

(i) the controlling timer,

(ii) the X-ray tube current, and

(iii) the current time product;

(l) where the equipment operates under automatic exposure control, the accuracy limits of that control; and

(m) the conditions under which the information provided under paragraphs (j) to (l) is valid.

Labelling

3. Diagnostic X-ray equipment must display the following information in a manner that is legible, permanent and visible on the specified surfaces:

(a) on the external surface of the main control panel

(i) a statement prohibiting unauthorized use and warning that hazardous X-rays are emitted when the equipment is in operation,

(ii) the X-ray warning symbol described in section 4, and

(iii) with respect to the X-ray generator,

(A) the name of the manufacturer,

(B) the model designation,

(C) the serial number,

(D) the date of manufacture, and

(E) the country of manufacture;

(b) on the external surface of the X-ray tube housing, with respect to the X-ray tube assembly,

(i) the name of the manufacturer,

(ii) the model designation,

(iii) the serial number,

(iv) the date of installation of the X-ray tube in the X-ray tube housing,

(v) the country of manufacture, and

(vi) the minimum permanent inherent filtration of the X-ray beam emitted from the X-ray tube assembly, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage;

(c) on the external surface of the X-ray tube housing or another suitable structure permanently attached to the X-ray tube housing

(i) an indicator that enables the focal spot to image receptor distance to be determined to within 2% of that distance, and

(ii) if the X-ray tube and the X-ray generator are not located within a common enclosure, marks that clearly indicate the anode and cathode terminals on the X-ray tube housing and on the high-voltage generator; and

(d) on the external surface of any beam limiting device that adds filtration to the X-ray beam, the total permanent filtration deliverable by the beam limiting device, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage.

4. The X-ray warning symbol shall

(a) be displayed in two contrasting colours;

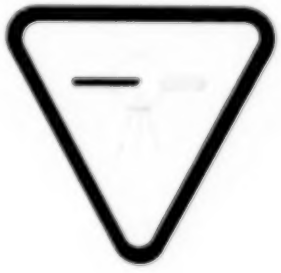
(b) be visible and identifiable from a distance of 1 m;

(c) be at least 2 cm high and at least 2 cm wide;

(d) bear the words "CAUTION: X-RAYS — ATTENTION : RAYONS X"; and

(e) conform to

(i) the following diagram:



or

(iii) symbol 03-03 in the report of the International Electrotechnical Commission entitled *Graphical symbols for electrical equipment in medical practice*, Publication 878, 1988, illustrated as follows:

5. All controls, meters, warning lights and other indicators required by this Part must be clearly labelled as to their function.

Construction Standards

General Requirements

6. Diagnostic X-ray equipment must have

(a) if more than one X-ray tube is controlled by one control panel,

(i) a visual indicator on or near each X-ray tube housing that shows that the X-ray tube to which the indicator applies is connected and ready to be energized, and

(ii) a visual indicator on the control panel that shows which of the X-ray tubes are connected and ready to be energized;

(b) a means, appropriate to the rectification type of the equipment, to compensate for variations in X-ray tube voltage caused by line voltage fluctuations;

(c) a visual or audible indicator that warns the operator when the variation in line voltage exceeds the rate set out in subsection 23(2) or a mechanism that, in that event, prevents X-rays from being emitted;

(d) on the control panel

(i) a warning light that indicates when the equipment is ready to be energized,

(ii) a second warning light that indicates when X-rays are being emitted,

(iii) if an automatic exposure control is provided, a visual indicator showing when that mode of operation is selected, and

(iv) if the automatic exposure control mode is not selected or does not exist, controls and visual indicators that enable the operator to select the loading factors before an irradiation;

(e) if the equipment is battery powered, a visual indicator on the control panel showing whether the battery is adequately charged for the proper operation of the equipment;

(f) a mechanism to initiate and terminate an irradiation;

(g) an audible signal to indicate the termination of an irradiation;

(i) if the equipment moves around a patient by remote control, an emergency stop switch that immediately terminates both the motion of the equipment and the emission of X-rays;

(j) a beam limiting device; and

(k) for equipment that operates within a range set out in column 1 of an item of the table to this paragraph, radiation filters that result in a measured half-value layer of aluminum of not less than

(i) for each X-ray tube voltage set out in column 2 of that item, the half-value layer set out in column 3 of that item, or

(ii) in any other case, the half-value layer obtained by linear interpolation or extrapolation from that table.

Table to paragraph 6 (k)
Minimum half-value layer of aluminum

Item	Column 1 Operating Range for Normal Use (kV)	Column 2 X-ray Tube Voltage (kV)	Column 3 Half-value Layer of Aluminum (mm)
1.	50 or less	(a) 20	0.3
		(b) 40	0.4
		(c) 50	0.5

7. (1) An irradiation switch for diagnostic X-ray equipment must

(a) permit the emission of X-rays only when the operator exerts continuous pressure on the switch;

(b) in the case of a foot switch, prevent the emission of any unintended X-rays when it is overturned; and

(c) in the case of mobile equipment, permit the operator to stand at least 3 m from the X-ray source when the X-ray tube is energized.

(2) The controlling timer for diagnostic X-ray equipment must

(a) automatically terminate an irradiation

(ii) on completion of a preset irradiation time,

(iii) on attainment of a preset current time product value, or

(iii.1) on completion of a preset number of X-ray pulses,

(b) permit the operator to terminate an irradiation at any time,

(c) automatically reset itself to its original setting or to zero on termination of an irradiation, and

(d) prevent the initiation of irradiation when the timer is set at zero, at the "off" position or at an unmarked setting.

8. (2) In the case of mammography equipment, when an object set out in column 1 of an item of the table to this subsection is positioned between the patient and the X-ray image receptor, the aluminum equivalent of the object shall not exceed the amount set out in column 2 of that item, as determined using an X-ray beam that

(a) is generated at an X-ray tube voltage of 30 kV,

(b) has a maximum X-ray tube voltage ripple of 10%, and

(c) has a half-value layer of aluminum of 0.3 mm.

Table to subsection 8(2)
Mammography equipment – maximum aluminum equivalent of interpositioned objects

Item	Column 1 Object	Column 2 Maximum Aluminum Equivalent (mm)
1.	Support table, excluding all layers	0.3

(3) For the purposes of subsection (2), any sensor used in automatic exposure control is a part of the X-ray image receptor.

9. For diagnostic X-ray equipment,

(a) the X-ray tube must be securely affixed to and aligned within the X-ray tube housing;

(b) the radiation filters must be securely affixed to the exit port of the X-ray tube housing or beam limiting device, or both; and

(c) the X-ray source assembly must maintain its required position or movement without drift or vibration during operation.

Radiographic Equipment

10. Radiographic equipment that is equipped with an automatic exposure control must have

(a) a means to automatically terminate the irradiation when

(i) if the operating X-ray tube voltage is less than 50 kV, the current time product exceeds 1 700 mAs per irradiation, and

(ii) when an irradiation under automatic exposure control terminates because the limit specified in paragraph (b) has been reached,

(i) a visual indicator or audible signal that warns the operator of the termination, and

(ii) a reset control that must be activated manually before another irradiation under automatic exposure control can be made.

15. (1) Mammography equipment must have

(a) a beam limiting device that limits the size of the X-ray beam to prevent the X-ray field, at any focal spot to image receptor distance at which the equipment operates, from extending

(i) more than 5 mm beyond the edge of the patient support next to the chest wall of the patient, and

(ii) more than a distance equivalent to 2% of the focal spot to image receptor distance beyond any other edge of the image reception area;

(b) an image receptor supporting device that

(i) has protective shielding that limits the residual radiation in accordance with section 26,

(ii) extends to the patient's chest wall, and

(iii) at every other edge, extends beyond the X-ray field by at least 1% of the focal spot to image receptor distance; and

(c) a breast compression device that

(i) is foot-actuated to start the compression,

(ii) permits fine adjustment of motion during the compression,

(iii) permits rapid decompression,

(iv) has motion adjustment controls on both sides of the position for the patient, and

(v) allows the portion of the compression plate in contact with the breast to be brought to within 10 mm of the surface of the patient support.

(2) Mammography equipment that has a removable, fixed-aperture beam limiting device must display the following information on its external surface:

(a) the dimensions of the image reception area, and

(b) the focal spot to image receptor distance at which the beam limiting device must be used.

Functioning Standards

21. Diagnostic X-ray equipment must function in accordance with the requirements set out in sections 22 to 32 during its operation under normal conditions of use.

22. (1) The definitions in this subsection apply in this section.

"coefficient of variation" means the ratio of the estimated standard deviation to the mean value of a series of measurements calculated using the equation:

$$C = \frac{S}{\overline{X}} = \frac{1}{\overline{X}}\left[\frac{\sum_{i=1}^{n}(X_i - \overline{X})^2}{n-1}\right]^{\frac{1}{2}}$$

where

C is the coefficient of variation;
S is the estimated standard deviation;
X_i is the value of the i^{th} measurement;
$\overline{X}$ is the mean value of the measurements; and
n is the number of measurements.
(*coefficient de variation*)

"exposure to the X-ray image receptor" means the amount of X-rays, registered by one or more detectors located in a fixed position in proximity to the X-ray image receptor, that is necessary to produce a radiogram of the overall density sought by the operator. (*dose d'irradiation au récepteur d'image radiologique*)

(2) For any combination of X-ray tube voltage, X-ray tube current and irradiation time, or for any selected exposure to the X-ray image receptor, when the line voltage for each measurement is accurate to within 1% of the mean line voltage value of all the measurements, and when all variable controls for the loading factors are adjusted to alternate settings and reset to the test setting before each measurement,

(a) the coefficient of variation of any 10 consecutive air kerma or exposure measurements, taken at the same point along the X-ray beam axis within a period of one hour, must be no greater than 0.05; and

(b) each of the 10 air kerma or exposure measurements taken under paragraph (a) must be within 15% of the mean value of those measurements.

(3) For the purposes of subsection (2), diagnostic X-ray equipment with an automatic exposure control must have attenuating material in the X-ray beam that is thick enough that the loading factors can be adjusted to provide single irradiations of at least

(a) 12 pulses, in the case of a field emission device that operates in pulse mode; or

(b) 0.1 s, in the case of any other diagnostic X-ray equipment.

23. (1) This section applies in respect of diagnostic X-ray equipment that has

(a) a high-voltage generator that is not a stored energy high-voltage generator;

(b) loading factors that do not change automatically to compensate for unintentional variations in X-ray tube voltage; and

(c) an irradiation time of at least 0.1 s and a current time product of at least 5 mAs.

(2) In the case of a line voltage regulation of 6% or less, the loading factor set out in column 1 of an item of the table to this subsection must not deviate from the selected value, for any combination of loading factors, by more than the quantity set out in column 2 of that item.

Table to subsection 23(2)
Maximum deviation of loading factors

Item	Column 1 Loading Factor	Column 2 Maximum Deviation from the Selected Value
1.	X-ray tube voltage of mammography equipment	5%
3.	Irradiation time	10% plus 1 ms
4.	X-ray tube current	20%
5.	Current time product	10% plus 0.2 mAs

24. (1) The controlling timer or automatic exposure control device of diagnostic X-ray equipment must have a minimum irradiation time capability that does not exceed the greater of:

(a) 1/60 s, or

(b) the time required to deliver a current time product of 5 mAs.

(2) If the automatic exposure control of diagnostic X-ray equipment is selected, the variation in optical density set out in subsection (4) must be determined using objects that are made of human-tissue equivalent material and have thicknesses that are representative of the actual range of the body thicknesses of the patients.

(4) The automatic exposure control device of mammography equipment, when both the X-ray tube voltage and the thickness of the objects described in subsection (2) are varied, must limit the variation in optical density of the resulting radiograms to 0.15.

25. (1) For any selected value of X-ray tube voltage within a range determined in accordance with subsection (2), the quotients of the average air kerma or exposure measurement divided by the indicated current time product, obtained at the applicable settings specified in subsection (3), must not differ by more than 0.10 times their sum as determined by the formula

$$|X_1 - X_2| \leq 0{,}1\,(X_1 + X_2)$$

where

X_1 is the quotient of the average air kerma or exposure measurement divided by the current time product determined at the first of the two applicable settings specified in subsection (3); and

X_2 is the quotient of the average air kerma or exposure measurement divided by the current time product determined at the second of the two applicable settings specified in subsection (3).

(2) The range referred to in subsection (1) is the smaller of

(a) 40% to 90% of the maximum available X-ray tube voltage, or

(b) the range of X-ray tube voltages specified for the diagnostic X-ray equipment by the manufacturer.

(3) The quotients referred to in subsection (1) must be determined at

(a) if the X-ray tube current is selected in discrete steps, any two consecutive X-ray tube current settings;

(b) if the X-ray tube current selection is continuous, any two X-ray tube current settings that differ by a factor of 2 or less;

(c) if the current time product is selected in discrete steps, any two consecutive current time product settings; or

(d) if the current time product selection is continuous, any two current time product settings that differ by a factor of 2 or less.

(4) If diagnostic X-ray equipment has more than one focal spot, the quotients referred to in subsection (1) must be determined for all combinations of two focal spots that have a nominal focal spot size greater than 0.45 mm, and all combinations of two focal spots that have a nominal focal spot size equal to or less than 0.45 mm at the applicable settings set out in subsection (3).

26. (1) For mammography equipment, the residual radiation behind the image receptor supporting device must not exceed an air kerma measurement of 1.0 μGy or an exposure measurement of 0.115 mR per irradiation when the equipment is operated at

(a) its maximum X-ray field and minimum focal spot to image receptor distance; and

(b) its maximum X-ray tube voltage and maximum current time product.

(2) For the purposes of subsection (1), the air kerma or exposure measurement must be averaged over a detection area that is 100 cm^2, of which no linear dimension is greater than 20 cm, centred at 5 cm from any accessible surface beyond the image receptor supporting device.

27. (1) Mammography equipment must have a minimum rate of radiation output of 7.0 mGy/s or 802 mR/s when the equipment is operated

(a) with a molybdenum anode and molybdenum filter;

(b) with the breast compression device in place between the X-ray source and the detector; and

(c) at an X-ray tube voltage of 28 kV in standard mammography mode at any focal spot to image receptor distance.

(2) For the purposes of subsection (1), the minimum rate of radiation output must be

(a) measured at a position that is 4.5 cm above the patient support; and

(b) averaged over a period of irradiation of 3.0 s.

29. (1) The leakage radiation from the X-ray source assembly of diagnostic X-ray equipment must not exceed an air kerma rate of 1.0 mGy/h or an exposure rate of 115 mR/h when the equipment is operated at the nominal X-ray tube conditions of loading that correspond to the maximum specified energy input in one hour.

(2) For the purposes of subsection (1), the rate must be averaged over a detection area of 100 cm^2, of which no linear dimension is greater than 20 cm, that is centred at 1 m from the focal point.

30. (1) If high voltage can appear across the X-ray tube of the diagnostic X-ray equipment, then the radiation emitting from the X-ray source assembly of the equipment must not exceed an air kerma rate of 20.0 μGy/h or an exposure rate of 2.3 mR/h when

(a) the equipment is operated with its beam limiting device fully open; and

(b) the automatic exposure control or the irradiation switch has not been activated.

(2) For the purposes of subsection (1), the rate must be averaged over a detection area of 10 cm^2, of which no linear dimension is greater than 5 cm, that is centred at 5 cm from any accessible surface of the X-ray source assembly.

31. (1) Under any operating condition, the radiation from any component of diagnostic X-ray equipment, other than the X-ray source assembly, must not exceed an air kerma rate of 20.0 μGy/h or an exposure rate of 2.3 mR/h.

(2) For the purposes of subsection 1, the rate must be averaged over a detection area of 10 cm^2, of which no linear dimension is greater than 5 cm, that is centred at 5 cm from any accessible surface of the component.

Appendix II:
Reference Documents

1. "CAR Standards and Guidelines for Breast Imaging." Canadian Association of Radiologists (1998). www.car.ca

2. "Mammography Accreditation Program." Canadian Association of Radiologists.

3. "Mammography Quality Control Manual 1999." American College of Radiology (1999).

4. "Organized Breast Cancer Screening Programs in Canada, 1997/1998 Report", Health Canada (2000).

5. "*Radiation Emitting Devices Act*." Revised Statutes of Canada, Chapter R-1, Ottawa (1985).

6. "*Radiation Emitting Devices Regulations*." Part XII, 'Diagnostic X-ray Equipment', Ottawa (2001)

7. "Safety Code 33, Radiation Protection in Mammography, Recommended Safety Procedures for the Use of Mammographic X-ray Equipment ." Environmental Health Directorate (1995).